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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 088/01161	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IL99/00670	International filing date (day/month/year) 08 DECEMBER 1999	(Earliest) Priority Date (day/month/year) 19 MARCH 1999
Applicant BY-PASS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

#### 1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).
3. ☐ Unity of invention is lacking (See Box II).

#### 4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

#### 5. With regard to the abstract,

- ☐ the text is approved as submitted by the applicant.
- ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No. 2f

- ☒ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.
- ☐ None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

## NEW ABSTRACT

An anastomotic connector for connecting a graft to a target vessel, comprising a thin collar section (104) adapted to engage a portion of the graft; and a separate spike section (124) adapted to mount on said collar section, and comprising a plurality of spikes (126) each of said spikes (126) adapted to transfix said graft. Preferably, the connector comprises at least one locking element for interlocking said spike section (124), and said collar section (104). Preferably the locking element provides a spring action between the two sections.

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL99/00670

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/04, 08  
US CL : 606/149, 153, 216

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
U.S. : 606/149, 153, 216

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
BRS  
Search Terms: punch, anvil, hole, ever\$, clos\$ or clamp\$ or scal\$, spike\$

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,695,504 A (GIFFORD, III et al.) 09 December 1997, entire document.	1-24, 36-45, 53-66, 73
X --- Y	US 4,018,228 A (GOOSEN) 19 April 1977, entire document.	67, 68, 70-71 ----- 46-48, 69, 72
Y,P	US 5,910,155 A (RATCLIFF et al.) 08 June 1999, entire document.	25-29, 30-35, 46-48, 52
Y	US 5,536,251 A (EVARD et al.) 16 July 1996, entire document.	25-35

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
08 JUNE 2000

Date of mailing of the international search report  
19 JUL 2000

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer  
JONATHAN GOLDBERG

Facsimile No. (703) 305-3230

Telephone No. (703) 308-0161

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IL99/00670

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 5,922,000 A (CHODOROW) 13 July 1999, entire document.	69, 72
X,P	WO 99/62408 A (DEROWE et al.) 09 December 1999, entire document.	1-73
X,P	US 5,976,159 A (BOLDUC et al.) 02 November 1999, entire document.	1-73
A,E	US 6,004,341 A (ZHU et al.) 21 December 1999.	25-35, 46-48, 52

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**PCT**  
**NOTIFICATION OF ELECTION**  
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 16 January 2001 (16.01.01)	
<b>International application No.</b> PCT/IL99/00670	<b>Applicant's or agent's file reference</b> 088/01161
<b>International filing date (day/month/year)</b> 08 December 1999 (08.12.99)	<b>Priority date (day/month/year)</b> 19 March 1999 (19.03.99)
<b>Applicant</b> LOSHAKOVE, Amir et al	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

19 October 2000 (19.10.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>Charlotte ENGER</p> <p>Telephone No.: (41-22) 338.83.38</p>
--	--

BEST AVAILABLE COPY PATENT COOPERATION TREATY

## PCT

NOTIFICATION CONCERNING  
AMENDMENTS OF THE CLAIMS(PCT Rule 62 and  
Administrative Instructions, Section 417)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE

in its capacity as International Preliminary Examining Authority

Date of mailing (day/month/year)

16 January 2001 (16.01.01)

International application No.

PCT/IL99/00670

International filing date (day/month/year)

08 December 1999 (08.12.99)

Applicant

BY-PASS, INC. et al

The International Bureau hereby informs the International Preliminary Examining Authority that no amendments under Article 19 have been received by the International Bureau (Administrative Instructions, Section 417).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Charlotte ENGER

Telephone No. (41-22) 338.83.38

RECEIVED

PATENT COOPERATION TREATY

15-10-2000

FENSTER &amp; Co.

PCT

From the INTERNATIONAL BUREAU

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1 (6) first sentence)

FENSTER, Paul  
Fenster & Company Patent  
Attorneys Ltd.  
P.O. Box 10266  
49002 Petach Tikva  
ISRAEL

Date of mailing (day/month/year)

28 September 2000 (28.09.00)

Applicant's or agent's file reference

088/01161

## IMPORTANT NOTICE

International application No.

PCT/IL99/00670

International filing date (day/month/year)

08 December 1999 (08.12.99)

Priority date (day/month/year)

19 March 1999 (19.03.99)

Applicant

BY PASS, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU, KP, KR, US

In accordance with Rule 47.1 (6) third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
- AE, AL, AM, AP, AT, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EA, EE, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, IL, IN, IS, JP, KE, KG, KZ, LG, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, OA, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- The communication will be made to those Offices only upon their request; furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 29.11a-bis).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 September 2000 (28.09.00) under No. WO 00/56226.

## REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

## REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.85

Authorized officer

J. Zahra

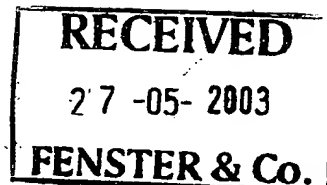
Telephone No. (41-22) 338.88.38

Form PCT/IB/308 (July 1996)

3537703



# PATENT COOPERATION TREATY



From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
MAIER FENSTER  
FENSTER & COMPANY PATENT ATTORNEYS, LTD.  
P.O. BOX 10256  
PETACH TIKVA, ISRAEL 49002

## PCT

COMMUNICATION IN CASES FOR WHICH  
NO OTHER FORM IS APPLICABLE

Applicant's or agent's file reference  088/01161	Date of Mailing (day/month/year) 08 MAY 2003  <b>REPLY DUE</b>  see paragraph 1 below
International application No.  PCT/IL99/00670	International filing date (day/month/year) 08 December 1999 (08.12.1999)
Applicant  BY-PASS, INC.	

1. ☐ REPLY DUE within \_\_\_\_\_ months/days from the above date of mailing

☒ NO REPLY DUE

2. COMMUNICATION:

The initial International Preliminary Examination Report (IPER) mailed by the IPEA/US on 12 OCT 2001 failed to take into consideration the response to the Written Opinion filed 07 AUG 2001. Further, the supplemental IPER mailed by the IPEA/US on 04 MAR 2003 failed to include all of the annexes and the statement regarding the industrial applicability of the claims (Box V-1) was inadvertently omitted. The Corrected IPER attached hereto includes all of the annexes and the statement regarding the industrial applicability of the claims. No other changes have been made.

Name and mailing address of the IPEA/US  
Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (703)305-3230

Authorized officer

Harry C. Kim

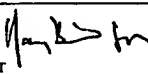
Telephone No. 703-308-2248

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01161	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL99/00670	International filing date (day/month/year) 08 December 1999 (08.12.1999)	Priority date (day/month/year) 19 March 1999 (19.03.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08, 17/04 and US Cl.: 606/153,149,184		
Applicant BY-PASS, INC.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>6</u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 19 October 2000 (19.10.2000)	Date of completion of this report 10 February 2003 (10.02.2003)	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer  Cary E. O'Connor Telephone No. 703-308-0858	

Form PCT/IPEA/409 (cover sheet)(July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL99/00670

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

☐

the international application as originally filed.

☒

the description:

pages 1-42 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_.

☒

the claims:

pages 47,48,51, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages 43,45,46,49,50, filed with the demand

pages 44, filed with the letter of 07 August 2001 (07.08.2001)

☒

the drawings:

pages 1-54, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_.

☐

the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐

the language of publication of the international application (under Rule 48.3(b)).

☐

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐

contained in the international application in printed form.

☐

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority in written form.

☐

furnished subsequently to this Authority in computer readable form.

☐

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:☒

the description, pages none

☒

the claims, Nos. none

☒

the drawings, sheets/fig none

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL99/00670

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 5 and 20

because:

- ☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5 and 20 are so unclear that no meaningful opinion could be formed (*specify*):

they are improper multiple dependent claims under PCT Rule 6.4(a) because they do not refer to the other claims in the alternative only.

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.  
☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/IL99/00670**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>14-19, 21-35, 41, 46-48, 50, 52, 55-73</u>	YES
	Claims <u>1-4, 6-13, 21-24, 36-40, 42-45, 49-51, 53, 54</u>	NO
Inventive Step (IS)	Claims <u>1-4, 6-19, 21-73</u>	YES
	Claims <u>none</u>	NO
Industrial Applicability (IA)	Claims <u>1-4, 6-19, 21-73</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Please See Continuation Sheet

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**V. 2. Citations and Explanations:**

Claims 1-4, 6-13, 42-45, 53 and 54 lack novelty under PCT Article 33(2) as being anticipated by Gifford (5,695,504). Gifford shows an anastomotic connector comprising a thin collar section 102, and a separate spike section 101 comprising a plurality of spikes 105. As to claims 42-45, 53 and 54, note Figs. 42A-42D. Spikes 524 are released from a compressed condition and retracted to engage the target vessel.

Claims 14-19, 21-24 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomotic connector comprising a base, a plurality of spikes and at least one spring element connected to a spike to allow resilient motion of the spike along the axis of the base.

Claims 49-51 lack novelty under PCT Article 33(2) as being anticipated by Smialowski (3,180,337). Smialowski teaches a method of everting a graft comprising grasping the graft between an internal mandrel 17 and an outer tube 25, and pushing an end of the graft over the graft (see Fig. 5).

Claims 25-35 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an apparatus for delivering a graft to an anastomosis comprising two coaxial tubular elements and a separator element mounted on one tubular element for splitting the other tubular element, and a method of using.

Claims 36-40 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector with spikes on one side of the ring with a transaxial thickening in the spikes, distanced from the ring.

Claim 41 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of containing and releasing an anastomotic connector having a thickening comprising containing the connector between two tubes with the thickening restrained by a protrusion on one of the tubes.

Claims 46-48 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a punch mechanism having two widening elements distal of the tip and defining a narrowing therebetween, and a coupling element for retracting the tip with relative motion of the widening elements to contract the narrowing.

Claim 52 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a graft everter having a graft stop and a plurality of expanding fingers.

Claims 55-63 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of simulating eversion of a graft wherein an end of the graft is compressed to form a thickening.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/IL99/00670

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Claim 64 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for transfixing a connector to a graft wherein the radius of the graft is increased without everting the graft and a spike of the connector is advanced such that it transfixes the end.

Claims 65 and 66 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a kit having a graft with a connector mounted to the ends and a guide wire attached to one end of the graft.

Claims 67-69 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an oblique hole punch comprising a first non-circular edge oblique to the shaft at a first angle, a second non-circular edge oblique to the shaft at a second angle, and means for reducing the gap between the edges.

Claims 70-72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a punch comprising a tip for puncturing the vessel, two surfaces for receiving the vessel walls, and means for bringing the surfaces together to punch a hole.

Claim 73 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of heat treating an anastomosis connector.

09/936806

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 16 OCT 2001

WIPO

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 088/01161	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL99/00670	International filing date (day/month/year) 08 December 1999 (08.12.1999)	Priority date (day/month/year) 19 March 1999 (19.03.1999)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08, 17/04 and US Cl.: 606/153,149,184		
Applicant BY-PASS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This **REPORT** consists of a total of 7 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19 October 2000 (19.10.2000)	Date of completion of this report 18 September 2001 (18.09.2001)
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Form PCT/IPEA/409 (cover sheet)(July 1998)



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL99/00670

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed.
- ☒ the description:  
pages 1-42 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 44,47,48,51 as originally filed  
pages none, as amended (together with any statement) under Article 19  
pages 43,45,46,49,50, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-54 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☒ The amendments have resulted in the cancellation of:**

- ☒ the description, pages none
- ☒ the claims, Nos. none
- ☒ the drawings, sheets/fig none

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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**III. N n-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 5 and 20

because:

- ☐ the said international application, or the said claim Nos. \_\_\_\_\_ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5 and 20 are so unclear that no meaningful opinion could be formed (*specify*):

They are improper multiple dependent claims under PCT Rule 6.4(a).

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.  
☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.  
☐ the computer readable form has not been furnished or does not comply with the standard.

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## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>25-41, 46-48, 50, 52, 55-73</u>	YES
	Claims <u>1-4, 6-19, 21-24, 42-45, 49, 51, 53, 54</u>	NO
Inventive Step (IS)	Claims <u>25-41, 46-48, 50, 52, 55-73</u>	YES
	Claims <u>1-4, 6-19, 21-24, 42-45, 49, 51, 53, 54</u>	NO
Industrial Applicability (IA)	Claims <u>1-73</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

### Continuation of Certain Documents Cited

#### 1. Certain published documents (Rule 70.10)

Application No	Publication Date	Filing Date	Priority date (valid claim)
<u>Patent No.</u>	<u>(day/month/year)</u>	<u>(day/month/year)</u>	<u>(day/month/year)</u>
None	None	None	None

#### 2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	Date of non-written disclosure <u>(day/month/year)</u>	Date of written disclosure referring to non-written disclosure <u>(day/month/year)</u>
None	None	None

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**International application No.  
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(To be used when the space in any of the preceding boxes is not sufficient)

**V. 2. Citations and Explanations:**

Claims 1-4, 6-13, 42-45, 53 and 54 lack novelty under PCT Article 33(2) as being anticipated by Gifford (5,695,504). Gifford shows an anastomotic connector comprising a thin collar section 102, and a separate spike section 101 comprising a plurality of spikes 105. As to claims 42-45, 53 and 54, note Figs. 42A-42D. Spikes 524 are released from a compressed condition and retracted to engage the target vessel.

Claims 14-19, 21-24 lack novelty under PCT Article 33(2) as being anticipated by Razgulov et al (3,908,662). In Figure 19, Razgulov shows an anastomotic connector comprising a base 34', a plurality of spikes 32, and at least one spring element 33 coupling the spikes to the base.

Claims 49,51 lack novelty under PCT Article 33(2) as being anticipated by Smialowski (3,180,337). Smialowski teaches a method of everting a graft comprising grasping the graft between an internal mandrel 17 and an outer tube 25, and pushing an end of the graft over the graft (see Fig. 5).

Claims 25-35 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an apparatus for delivering a graft to an anastomosis comprising two coaxial tubular elements and a separator element mounted on one tubular element for splitting the other tubular element, and a method of using.

Claims 36-40 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an anastomosis connector with spikes on one side of the ring with a transaxial thickening in the spikes, distanced from the ring.

Claim 41 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of containing and releasing an anastomotic connector having a thickening comprising containing the connector between two tubes with the thickening restrained by a protrusion on one of the tubes.

Claims 46-48 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a punch mechanism having two widening elements distal of the tip and defining a narrowing therebetween, and a coupling element for retracting the tip with relative motion of the widening elements to contract the narrowing.

Claim 52 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a graft everter having a graft stop and a plurality of expanding fingers.

Claims 55-63 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of simulating eversion of a graft wherein an end of the graft is compressed to form a thickening.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Claim 64 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method for transfixing a connector to a graft wherein the radius of the graft is increased without everting the graft and a spike of the connector is advanced such that it transfixes the end.

Claims 65 and 66 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a kit having a graft with a connector mounted to the ends and a guide wire attached to one end of the graft.

Claims 67-69 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an oblique hole punch comprising a first non-circular edge oblique to the shaft at a first angle, a second non-circular edge oblique to the shaft at a second angle, and means for reducing the gap between the edges.

Claims 70-72 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a punch comprising a tip for puncturing the vessel, two surfaces for receiving the vessel walls, and means for bringing the surfaces together to punch a hole.

Claim 73 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a method of heat treating an anastomosis connector.

## CLAIMS

1. An anastomotic connector for connecting a graft to a target vessel, comprising:  
a thin collar section, adapted to engage a portion of the graft; and  
5 a separate spike section, adapted to mount on said collar section and comprising a plurality of spikes, each of said spikes adapted to transfix said graft and penetrate said target vessel.
2. A connector according to claim 1, comprising at least one locking element for  
10 interlocking said spike section and said collar section.
3. A connector according to claim 2, wherein said locking element is formed on said collar portion.
- 15 4. A connector according to claim 3, wherein said locking element mates with an aperture defined by said spike section.
5. A connector according to any of claims 2-4, wherein said locking element provides a spring-action, which action resists relative motion axial between at least part of said spike  
20 section and at least part of said collar section, with a force dependent on the range of motion.
6. A connector according to claim 1, wherein said spike section comprises a super-elastic material.
- 25 7. A connector according to claim 1, wherein said spikes are pre-bent in a hook shape, such that said hook shape is adapted to engage the target vessel.
8. A connector according to claim 1, wherein said collar element comprises a plurality of flange elements proximal to said target vessel.  
30
9. A connector according to claim 8, wherein said flange elements define apertures for said spike elements to pass through.

10. A connector according to claim 9, wherein said flange elements include at least one opening in their perimeter, wide enough for one of said spikes to be brought in through.
11. A connector according to claim 1, wherein said collar section defines a cylindrical  
5 volume.
12. A connector according to claim 1, wherein said collar section is adapted to form a perpendicular anastomosis.
- 10 13. A connector according to claim 1, wherein said collar section is adapted to form an oblique anastomosis.
14. An anastomotic connector for connecting a graft to a target vessel, comprising:  
a base for engaging said graft;  
15 a plurality of spikes for transfixing said graft and engaging said target vessel; and  
at least one spring element attached to at least one of said spikes, which spring element  
couples a connection between said spike and said base and allows resilient motion of said  
spike along an axis of said base.
- 20 15. A connector according to claim 14, wherein said spikes and said base form a single element.
16. A connector according to claim 14, wherein said spikes and said base form two  
separate elements.
- 25 17. A connector according to claim 14, wherein said spring comprises a flat coil spring.
18. A connector according to claim 14, wherein said spring comprises a leaf spring.
- 30 19. A connector according to claim 14, wherein said at least one spring comprises at least two springs in series.
20. A connector according to any of claims 14-19, wherein, each of said spikes has at least one independent associated spring.



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21. A connector according to claim 14, wherein said connector is configured for performing an oblique anastomosis.
- 5 22. A connector according to claim 14, comprising at least one tab associated with one spike of said spikes, for moving said spike.
23. A connector according to claim 22, wherein said tab is adapted for retracting said spike.
- 10 24. A connector according to claim 22, wherein said tab is adapted for advancing said spike.
25. Apparatus for delivering a graft to an anastomosis, comprising:  
15 at least two tube-like coaxial elements, each defining an aperture adapted for inserting said graft such that the graft exits through a first end of said tube-like elements;  
at least one separator element mounted on at least one of said tube-like elements for splitting the other of said tube like elements, so the graft can be removed through a resulting slot, which slot spans said first end and said aperture.
- 20 26. Apparatus according to claim 25, wherein said at least one separator comprises a knife which cuts said slit.
27. Apparatus according to claim 25, wherein said at least one separator comprises a  
25 spreader which widens an existing slit in said tube to form said slot.
28. Apparatus according to claim 25, comprising an outer tube which prevents said tube from splitting unless it is sufficiently retracted.
- 30 29. Apparatus according to claim 25, wherein said tube-like elements are adapted to carry an anastomotic device between them.
30. A method of detaching a graft delivery tool from an enclosed graft, comprising:  
splitting apart said tool, to form a slot, using a slot-forming element; and

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removing said graft through said slot.

31. A method according to claim 30, wherein said slot-forming element comprises a knife that splits said tool.

32. A method according to claim 30, wherein said slot-forming element comprises a spreader that widens an existing slit in said tool.

33. A method according to claim 30, comprising:  
retracting at least one tube that encloses said graft.

34. A method according to claim 33, wherein said retracting urges said tube against a slot forming element.

35. A method according to claim 30, comprising moving said slot-forming element relative to said tool, to form said slot.

36. An anastomosis connector comprising:  
a ring shaped base having an axis;  
at least one plurality of spikes on one side of said ring wherein said spikes are adapted to not penetrate a graft on which said connector is mounted prior to being attached to a target vessel; and  
at least one transaxial thickening in at least one of said spikes, distanced from said ring.

37. A connector according to claim 36, comprising a second plurality of spikes pointing in an opposite direction from said first set of spikes.

38. A connector according to claim 36, wherein said thickening comprises a point where said spike splits into tines.

39. A connector according to claim 38, wherein said tines are shorter than a thickness of a target blood vessel for which the connector is designed.

40. A connector according to claim 36, wherein said at least one plurality of spikes do not apply radial pressure towards or away from said ring, once deployed.

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54. A method according to claim 53, wherein changing the configuration comprises releasing said spikes.
  
55. A method of simulating eversion of a graft, comprising:  
 5 compressing an end of said graft into a form to provide a thickening of said end; and  
 transfixing said thickening with at least one spike of an anastomosis connector.
  
56. A method according to claim 55, wherein said graft comprises a mammary artery.
  
- 10 57. A method according to claim 55, wherein said transfixing comprises transfixing along an axis of said graft.
  
58. A method according to claim 55, wherein said transfixing comprises transfixing oblique to an axis of said graft.
  
- 15 59. A method according to claim 55, wherein said transfixing comprises transfixing perpendicular to an axis of said graft.
  
60. A method according to claim 55, wherein said form comprises an inner mandrel.
  
- 20 61. A method according to claim 55, wherein said form defines, on said graft, a flat end surface for said thickening.
  
62. A method according to claim 55, wherein said form defines, on said graft, an oblique  
 25 end surface for said thickening.
  
63. A method according to claim 55, wherein said form defines, on said graft, a non-planar end surface for said thickening.
  
- 30 64. A method of transfixing a connector on a graft, comprising:  
 increasing a radius of an end of the graft without everting the graft;  
 advancing at least one spike of said connector, parallel to said graft, such that it  
 transfixes said radius increased end; and

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bending at least an end of said spike to form a hook.

65. A kit for a bypass procedure, comprising:  
at least one graft having anastomosis connectors mounted on two ends thereof, said  
5 graft and said connectors adapted for a peripheral bypass procedure; and  
at least one guide wire attached to one end of said graft.
66. A kit according to claim 65, wherein said connectors are embedded in said ends of said  
graft.
- 10 67. An oblique hole punch, comprising:  
a shaft;  
a first non-circular edge oblique to said shaft at a first angle;  
a second non-circular edge oblique to said shaft at a second angle; and  
15 means for reducing a gap between said two edges, so as to cut through vascular tissue  
placed between them.
68. A punch according to claim 67, wherein said two angles are different.
- 20 69. A punch according to claim 67, wherein said two angles are the same.
70. A penetrating punch for punching holes in a blood vessel during a keyhole procedure,  
comprising:  
a tip for puncturing said vessel;  
25 a rigid handle, adapted for keyhole surgery and coupled to said tip, for controlling a  
spatial position of said tip;  
two surfaces for receiving the walls of the vessel surrounding said puncture; and  
means for bring said surfaces together for punching said hole.
- 30 71. A punch according to claim 70, wherein said tip is smooth.
72. A punch according to claim 70, wherein said tip is axially grooved.

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